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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,438	11/14/2003	Douglas G. Evans	KN P 0131	9636

7590

06/27/2005

Jeffrey C. Kelly
Kensley Nash Corporation
55 East Uwchlan Avenue
Exton, PA 19341

EXAMINER

BLANCO, JAVIER G

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 06/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/713,438

Applicant(s)

EVANS ET AL.

Examiner

Javier G. Blanco

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on June 13, 2005.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 13, 2005 has been entered.

Response to Amendment

2. Applicants' amendment of claims 1, 3, 7, 8, 30, and 34 in the reply filed on June 13, 2005 is acknowledged.
3. Applicants' cancellation of claim 35 in the reply filed on June 13, 2005 is acknowledged.

Specification

4. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: "tissue conductive matrix" (see claims 1, 30, and 34).

Claim Objections

5. Claims 1, 30, and 34 are objected to because of the following informalities:
- a. Regarding claim 1, please substitute "or paste," (see line 6) with --or paste prior to implantation,--. Appropriate correction is required.

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- b. Regarding claim 30, please add --soluble-- after “flowable” (see line 7). Appropriate correction is required.
- c. Regarding claim 30, please add --non-soluble-- after “hold the” (see line 7). Appropriate correction is required.
- d. Regarding claim 34, please substitute “fiber:” (see line 4) with --fiber;--. Appropriate correction is required.
- e. Regarding claim 34, please add --ceramic-- in front of “granules” (see line 6). Appropriate correction is required.
- f. Regarding claim 34, please add --the non-soluble collagen-- in front of “fibers” (see line 6). Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 30-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- a. Regarding claim 30, the subject matter claimed therein is indefinite as to the scope of the invention. Claim 30 at line 3 claims “a non-soluble collagen fiber”, while at line 7 claims “the collagen fibers”. Is it --fiber-- or --fibers--? Claims 31-33 depend on claim 30.

b. Regarding claim 34, the subject matter claimed therein is indefinite as to the scope of the invention. Claim 34 at line 4 claims “a non-soluble collagen fiber”, while at line 6 claims “and fibers”. Is it --fiber-- or --fibers--?

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1-34 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Yamamoto et al. (US 2002/0183855; cited in Applicants' IDS).

Yamamoto et al. disclose an implant for the repair or regeneration of tissue (see entire document). Said implant is porous, biodegradable, three-dimensionally fixed, has shape memory, and maintains physical/structural integrity and porosity after been implanted (see entire document).

a. At least a first component of the implant is a non-soluble ceramic microgranules/microparticulate (i.e., calcium phosphate, hydroxyapatite; see page 2, paragraph 0020; page 3, paragraph 0036).

b. At least a second component is a non-soluble natural collagen fiber (i.e., insoluble fibrillar collagen; see page 1, paragraph 0015) obtained from either mineralized or unmineralized collagen sources (see page 2, paragraph 0015).

c. At least a third component is a non-porous collagen gel (see page 2, paragraphs 0024-0027).

Besides maintaining physical/structural integrity and porosity after been implanted, another property of the resulting matrix is the capability of been compressible from an initial size, shape, and porosity, and returning, from a compressed state, to its initial size, shape, and porosity (see page 3, paragraph 0031). Said matrix further comprising: proteins, growth factors, bone marrow, and drugs (see page 2, paragraph 0022; page 3, paragraph 0037). Also, said matrix is cross-linked (i.e., glutaraldehyde; see page 2, paragraph 0028; page 3, paragraph 0032) and sterilized (i.e., ethylene oxide; see page 3, paragraph 0033). The matrix or slurry can be lyophilized (see page 2, paragraph 0028) and can also be hydrated prior to or following implantation (see page 5, paragraphs 0054-0056). Further, said matrix can be compressed during the implant procedure (see page 3, paragraph 0034) or prior to the implant procedure (see page 4, paragraph 0046). The proportions of insoluble (i.e., fibrillar mineralized or unmineralized collagen) to soluble collagen are disclosed in page 2, paragraphs 0023 and 0027. The matrix can be delivered via a delivery vehicle such as a cannula (see page 3, paragraph 0034).

It is noted that most any material is capable of being plastically or permanently deformed if subjected to a very high stress. As disclosed in Yamamoto et al. paragraph 0037, the matrix has many applications such as tissue or cartilage repair, or osteoconductive bone grafting material for spinal fusion, filling bone defects, fracture repair, and grafting periodontal defects. Most of these applications will present stresses to the matrix when implanted. It should be noted that “filling bone defects” and “fracture repair” comprise irregularly shaped voids or defects. What this means is that some (if not all) of the matrix covering or filling these areas will never return to its original shape and/or size. Also, Yamamoto et al. matrix comprises the same

materials as Applicants' matrix, using the same ratios and consistency, and intended for the same purpose(s). The results will inherently be the same.

Response to Arguments

10. Applicant's arguments filed June 13, 2005 have been fully considered but they are not persuasive. Applicants argue: "The implant of Yamamoto has shape memory (see, for example, paragraphs [0031] and [0034]). In contrast, the claimed implant has a paste consistency."

Examiner respectfully disagrees. Newly added claim language of claims 30 and 34 broadly claim said implant as "having a consistency of a putty or paste prior to implantation and retains at least some compliance following implantation". There is nothing in Yamamoto et al. 2002/01833855 that deviates from said broad claim language. The implant of Yamamoto et al. has a paste/putty consistency ("slurry"). The term "compliance" is generally defined as (i) "a physical quality of yielding to pressure or force without disruption"; and (ii) "a measure of the ease with which a structure or substance may be deformed". Based on these two definitions, the implant of Yamamoto et al. will retain "at least some compliance" following implantation since (i) it comprises the same materials as Applicants' matrix (as claimed); and (ii) it is intended for the same purpose(s) as Applicant's matrix (e.g., spinal fusion, filling regular or irregular bone defects, fracture repair, and grafting periodontal defects).

(i) Under M.P.E.P. 2113.03, the transitional term "comprising" is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997).

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(ii) It is the claims that define the claimed invention, and it is claims, not specifications that are anticipated or unpatentable. *Constant v. Advanced Micro-Devices Inc.* 7 USPQ2d 1064.

Conclusion

11. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (7:30 a.m.-4:00 p.m.), first Friday of the bi-week off.


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned is 703-872-9306 for regular communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

JGB

A stylized handwritten signature consisting of several loops and a vertical stroke.

June 21, 2005

A handwritten signature in cursive script, appearing to read 'D. Willse'.

David H. Willse
Primary Examiner